DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
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GS1944

December 21, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUEST
Haruhisa Yamamoto
President
Denver Tofu Company, Inc.
3825 Blake Street
Denver, Colorado 80205-3319

Ref#: Den 05-05

Dear Mr. Yamamoto:

The Food and Drug Administration (FDA) collected a sample of your product, Kinugoshi silken tofu, packaged in 16-ounce trays with cellophane lids, on September 13, 2004 during a visit to your manufacturing facility. The samples were collected to determine your firm's compliance with the Federal Food, Drug, and Cosmetic Act (the Act) and its implementing regulations in Title 21, Code of Federal Regulations. You can find the Act and regulations on FDA's web site at www.fda.gov.

Our analysis of the Kinugoshi silken tofu, code "14 OCT 04", found that the product is misbranded under section 403(a)(1) of the Act in that the labeling is false or misleading because the amount of calcium present is less than the amount declared (see 21 CFR 101.9(g)(4)(i)). The label declares that the product provides 15% of the Daily Value (DV) of calcium per serving; however, our analysis found the calcium content to be 29.3% (original analysis) and 29.1% (check analysis) of the value declared in the nutrition information on the label.

This letter does not represent a comprehensive review of all of the products distributed by your firm, nor does it represent a complete review of all product labeling and nutrient content. You must ensure all products distributed by your firm comply with the Act and its implementing regulations. Failure to make prompt corrections may result in further enforcement action being initiated by the Food and Drug Administration. This could include seizure of illegal products and/or injunction against your firm.

Please respond to this office in writing within 15 working days of receipt of this letter. Your response should outline the specific things you are doing to correct this deviation and to prevent its recurrence. If you cannot complete all corrections before you respond, please state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to Compliance Officer Shelly L. Maifarth at the address indicated in the letterhead. She may be reached at (303) 236-3046.

Sincerely,

B. Belinda Collins
District Director